DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

April 5, 2016

GIMMI Gmbh
% Ms. Dagmar S. Mäser
FDA Laison
Business Support International
1017 AP Amsterdam
Amstel 320-I
The Netherlands

Re: K012660
Trade/Device Name: GIMMI ALPHA®
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: FAJ, FBK, FDC, FDE, FED, FGC, FJL, GCJ, FET, GCT, EZO, FAS KNS, KQT, FBM, LQR, FHA, KOD, KOE, GEI, FCL, MNL, KOA, FAX, GBZ, FSM and GEA
Dated (Date on orig SE ltr): October 17, 2001
Received (Date on orig SE ltr): October 19, 2001

Dear Ms. Mäser,

This letter corrects our substantially equivalent letter of July 27, 2015.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -S

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number K012660

Device Name **ALPHA® Endoscopic Instruments & Accessories**

INDICATIONS FOR USE

GIMMI *ALPHA*® Gastro-Urology and Laparoscopic Endoscopes, Endoscopic Accessories and GIMMI devices for minimally invasive gastrointestinal (GI), genitourinary (GU), and laparoscopic diagnostic and/or therapeutic indications are intended to be used by qualified physicians to provide access, illumination and visualization of internal structures and for manipulating soft tissue (grasping, cutting, coagulating, dissecting and suturing) in a wide variety of diagnostic and therapeutic laparoscopic/urologic and minimally invasive procedures.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____

(Per CFR 801 109)

(Optional Format 1-2-96)

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K012660

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2. 510(k) SUMMARY of Safety and Effectiveness

GIMMI GmbH

As required by Section 807.92(c)

2.1 Submitter: [807.92 (a)(1)]

GIMMI GmbH
Junkerstr. 1
D-78532 Tuttlingen
Germany

Tel. +49-7461 - 9 65 90-0
Fax +49-7461 – 9 65 90-33
e-mail info@gimmi.de

2.2 Contact Person: [807.92 (a)(1)]

Dagmar S. Mäser
Business Support International
Amstel 320-I
1017 AP Amsterdam
The Netherlands

Tel. +31-20-428 95 91
Fax +31-20-428 94 29
eMail bsi@xs4all.nl

2.3 Date Summary Prepared: [807.92 (a)(1)] December 10, 2001

2.4 Device Names: [807.92 (a)(2)]

Proprietary GIMMI *ALPHA®* gastro-urology and laparoscopic endoscopes, endoscopic accessories and GIMMI devices for minimally invasive GI, GU, and laparoscopic diagnostic and/or therapeutic indications.

Common Endoscopic Instruments & Accessories and Minimally Invasive GI and GU Devices

PANEL 78			
Cystoscope, Diagnostic	78 FAJ	876.1500	II
Needle, Endoscopic	78 FBK	876.1500	II
Resectoscope & Accessories	78 FDC	876.1500	II
Set, Laparoscope	78 FDE	876.1500	II
Sheath, for Endoscope	78 FED	876.1500	II
Urethroscope	78 FGC	876.1500	II
Resectoscope	78 FJL	876.1500	II
Laparoscope, General & Plastic Surgery	78 GCJ	876.1500	II
Endoscopes & Accessories	78 K0G	876.1500	II
Urethrotome	78 EZO	876.4770	II
Electrode, Electrosurgical,. Active, Urol	78 FAS	876.4300	II
Unit, Electrosurgical,	78 KNS	876.4300	II
Minimally Invasive GI and GU Devices			
Evacuator, Gastro-Urology	78 KQT	876.4370	II
Cannula and Trocar, Suprapubic	78 FBM	876.5090	II

Dislodger, Stone Biliary	78LQR	876.5010	II
Clamp, Penile	78 FHA	876. 5160	II
Catheter, Urological	78 KOD	876.5130	II
Dilator, Urethral	78 KOE	876.5520	II
PANEL 79			
Device, Electros., Cutting & Coag'n & Acc	79 GEL	878.4400	II
PANEL 78: EXEMPT DEVICES			
Forceps, Biopsy, Non-Electric	78 FCL	876.1500	I Exempt
Accessories, Cleaning Brushes for Endoscope	78 MNL	876.1500	I Exempt
Surg Instruments,G-U, Manual & Acces	78 KOA	876.4300	I Exempt
Bougies, Urological	78 FAX	876.5520	I Exempt
PANEL 79: EXEMPT DEVICES			
Catheter, Cholangiography	79 GBZ	878.4200	I Exempt
Tray, Surgical, Instrument	79 FSM	878.4800	I Exempt
Cannula, Surgical, General & Plastic Surg	79 GEA	878.4800	I Exempt

2.5 Reason for Submission:

New Devices

2.6 Predicate Devices: [807.92 (a)(3)]

Predicate devices are produced by

Günter Bissinger Medizintechnik
Comeg Endoscopy
Dufner Instrumente GmbH
Henke-Sass Wolf, GmbH
Optus, Inc.
Pilling Weck Group
Wolf
Karl Storz Endoscopy
and a wide range of other manufacturers, including:
Jarit (J. Jamner Surgical Instruments, Inc.)
Snowden-Pencer, Inc.
SurgiTech, Inc. (Surgical Technologies International, Inc.)
United States Surgical Corp.
Allegiance Healthcare Corp.

2.7 Device Description: [807.92(a)(4)+(6)]

GIMMI *ALPHA* Endoscopes are comprised of rigid, panoramic telescopes using rod lens technology. The body contact portions are composed of surgical grade stainless steel, which is commonly used in medical devices for a wide range of applications and has a long history of biocompatibility for human use.

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Laparoscopic and urological-gastroenterologic and related accessories are composed of reusable handle and shaft assemblies and removable, reusable tip assemblies. Needle holders and other Class I devices included in the endoscopic catalogs may be one-piece. The instruments are designed and manufactured specifically for the purpose of manipulating soft tissue structures (grasping, cutting, dissecting, coagulating and suturing).

Minimally Invasive GI and GU Devices are design specific for short term use in diagnostic and/or therapeutic procedures

2.8 Intended Use: [807.92 (a)(5)]
GIMMI *ALPHA*® gastro-urology and laparoscopic endoscopes, endoscopic accessories and GIMMI devices for minimally invasive GI, GU, and laparoscopic diagnostic and/or therapeutic indications are intended to be used by qualified physicians to provide access, illumination and visualization of internal structures and for manipulating soft tissue (grasping, cutting, coagulating, dissecting, and suturing) in a wide variety of diagnostic and therapeutic laparoscopic/urologic closed and minimally invasive procedures.

2.9 Industry Standards/Performance Data: [807.92 (d)]
GIMMI certifies compliance with relevant ISO/EN/ASTM/ AAMI/ANSI/IEC and other device-related standards that apply to the manufacture, packaging, labeling, and reprocessing of subject devices including the validation of these processes.

2.10 Summary of Testing
All materials used in the composition of GIMMI *ALPHA*® gastro-urology and laparoscopic endoscopes, endoscopic accessories and GIMMI devices for minimally invasive GI, GU, and laparoscopic diagnostic and/or therapeutic indications were subjected to performance and physical tests to evaluate safety, effectiveness, and reliability of the devices. All results were in conformance with the cited harmonized device standards.

2.11 Information Bearing on the Safety and Effectiveness: [807.92 (b)(3)]
The GIMMI *ALPHA*® gastro-urology and laparoscopic endoscopes, endoscopic accessories and GIMMI devices for minimally invasive GI, GU, and laparoscopic diagnostic and/or therapeutic indications have the same intended use as predicate devices. They are made of the same material and produced to the same international and FDA-recognized standards. Slight modifications in design do not adversely affect the safety and effectiveness of these devices.

In summary, the

- intended use
- performance attributes
- materials and
- basic design

are identical (endoscopes and HF accessories) and identical/ substantially equivalent to SE devices.

The results of design validation raise no new issues of safety and effectiveness.